AUG 2 8 2012

510(k) SUMMARY

Manufacturer/Owner : TERUMO (PHILIPPINES) CORPORATION
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Date prepared : June 22, 2012

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A. DEVICE NAME

Proprietary Name

TERUMO® SurGuard®3 Safety Hypodermic Needle
TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle

Classification Name

Hypodermic Single Lumen Needle (880.5570) with antistick

Product Code: 80FMI / 80MEG

Classification: Class II

Common Name

Hypodermic Needle with Safety Sheath or Needle with needle protection device.

B. INTENDED USE

The Terumo SurGuard®3 Safety Hypodermic Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The Terumo SurGuard®3 Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Note: This is the same intended use as the predicate device, Terumo SurGuard®3 Safety Hypodermic Needle.

C. DEVICE DESCRIPTION

The Terumo® SurGuard®3 Safety Hypodermic Needle consists of a hypodermic needle with a hinged safety sheath attached to the connector hub with or without an attached hypodermic syringe. This device features a hinged safety sheath attached to the needle hub. The safety sheath contains two locking mechanisms, the tooth-cannula and sheath-collar which are simultaneously activated when

manually pressed over the needle immediately after use and just prior to disposal to minimize the possibility of sharps injury. The safety sheath is activated with a one-handed operation by pressing the sheath either by finger, thumb or surface activation.

The safety sheath has a finger guide area consisting of a circular dent (for thumb activation) and ramp (for finger activation) which gives the user a concrete confirmation that the user's finger is in the appropriate position in performing the activation. The ramp has steps to provide strong grasp when activating the sheath. There are two stoppers located at the end of the circular dent and ramp which prevent the user's finger from going towards the cannula during activation. Another method of activation is by manually pressing the safety sheath over the needle using a firm surface.

The locking mechanisms are positioned within the center and proximal end of the sheath. The hinge feature allows the medical practitioner to flexibly adjust the sheath to its desired position for use.

The Terumo SurGuard®3 Safety Hypodermic Needle will be individually packaged and sterilized by electron beam as a safety needle only or as a safety needle with attached Terumo syringe.

D. SUBSTANTIAL EQUIVALENCE

The Terumo SurGuard®3 Safety Hypodermic Needle and with attached syringe submitted in this 510(k) and manufactured by Terumo (Philippines) Corporation is substantially equivalent to:

1. K113422 TERUMO® SurGuard® 3 Safety Hypodermic Needle with or without syringe manufactured by Terumo (Philippines) Corporation.

E. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Principle of Operation and Technology

The Terumo® SurGuard®3 Safety Hypodermic Needle device with and without syringe manufactured by Terumo (Philippines) Corporation, subject of this 510(k), and the predicate devices covered under K113422 are operated manually.

Materials

All materials for the Terumo SurGuard®3 Safety Hypodermic Needle and with attached syringe are the same as the materials of the SurGuard3 as submitted in the 510(k), K113422. The 1 cc/ml syringe plunger is made up of polystyrene, while the 3, 5, and 10 cc/ml syringes utilize polypropylene for the plunger; however, both polystyrene and polypropylene were cleared for use in the plunger under K113422.

Specifications

The new needle gauge sizes to be added under this 510(k) are 26G, 27G, 30G and the new needle lengths are 3/8", 5/8", and 1/2". The syringe size to be added is 1cc/ml, as K113422 only provided for 3, 5, and 10 cc/ml syringe and needle combinations. This submission also provides for new needle gauge and length combinations for 23G and 25G needles and 1" needle length which were cleared under K113422. Finally, this submission includes the shorter safety sheath with modified design for all new gauge and needle length combinations.

The proposed Terumo SurGuard®3 Safety Hypodermic Needle comes with a shorter safety sheath. The inside rib design of the sheath was modified, specifically extending rib 2 towards the inside wall of the sheath and modifying rib 3 to be symmetrical. This design allows the cannula to slide towards the center of the sheath during the activation.

For further clarification of the reason for this submission and differences from the previous 510(k), Tables 1 and 2 on the following page are included here. Table 1 shows the needle gauges x needle length combinations both new for this submission and those cleared under previous 510(k), K113422. Table 2 demonstrates gauge and needle length combinations and the syringe size specific to each needle gauge x needle length. "X" demonstrates clearance under previous 510(k), K113422, while items new for this submission are denoted by "New."

Table 1 – Needle Gauges x Needle Length

TABLE 1		Needle Length					
		3/8" (9mm)	1/2" (13mm)	5/8" (16mm)	1" (25mm)	1 1/2" (38mm)	2" (51mm)
Gauge Size	18G				X	X	
	19G				X	X	
	20G				X	X	X
	21G				X	X	
	22G				X	X	
	23G				New	X	
	25G			New	New	X	
	26G	New	New				
	27G		New				
	30G		New				

Table 2 – Needle Length and Gauge x Syringe

TABLE 2		Syringe Size			
		1 cc/ml	3 cc/ml	5 cc/ml	10 cc/ml
Needle Gauge x Needle Length	18G x 1"				
	18G x 1 ½"				
	19G x 1"				
	19G x 1 ½"				
	20G x 1"		X	X	X
	20G x 1 ½"		X	X	X
	20G x 2"				
	21G x 1"		X		X
	21G x 1 ½"		X	X	
	22G x 1"		X		
	22G x 1 ½"		X		
	23G x 1"		New		
	23G x 1 ½"				
	25G x 5/8"	New	New		
	25G x 1"		New		
	25G x 1 ½"				
	26G x 3/8"	New			

TABLE 2		Syringe Size			
		1 cc/ml	3 cc/ml	5 cc/ml	10 cc/ml
Needle Gauge x Needle Length	26G x ½"				
	27G x ½"	New			
	30G x ½"				

The above cleared devices (indicated as "X") serve as predicate for the devices that are subject of this 510(k).

Specifications for product proposed in this 510(k)

Product Code	Description
SG3-2325	23gauge x 1" (25mm) safety hypodermic needle
SG3-2516	25gauge x 5/8" (16mm) safety hypodermic needle
SG3-2525	25gauge x 1" (25mm) safety hypodermic needle
SG3-2609	26gauge x 3/8" (9mm) safety hypodermic needle
SG3-2613	26gauge x 1/2" (13mm) safety hypodermic needle
SG3-2713	27gauge x 1/2" (13mm) safety hypodermic needle
SG3-3013	30 gauge x 1/2" (13mm) safety hypodermic needle
SG3-01T2516	25gauge x 5/8" (16mm) safety hypodermic needle, with 1cc/ml syringe
SG3-01T2609	26gauge x 3/8" (9mm) safety hypodermic needle, with 1cc/ml syringe
SG3-01T2713	27gauge x 1/2" (13mm) safety hypodermic needle, with 1cc/ml syringe
SG3-03L2325	23gauge x 1" (25mm) safety hypodermic needle, with 3cc/ml syringe
SG3-03L2516	25gauge x 5/8" (16mm) safety hypodermic needle with 3cc/ml syringe
SG3-03L2525	25gauge x 1" (25mm) safety hypodermic needle with 3cc/ml syringe

Performance

The following tests were performed on the Terumo SurGuard®3 Safety Hypodermic Needle and with attached syringe.

Performance Testing

These tests were performed on both predicate device K113422 and the proposed device:

- Sheath Activation
- Sheath Deactivation
- Sheath Removal
- Sheath Radial
- Sheath Retraction
- Protector Fitting
- Collar removal
- Sheath Puncture
- Adhesive Hold
- Needle Penetration
- Manual Sheath Activation
  - Finger Activation
  - Thumb Activation
  - Surface Activation
- Measurement Testing
- Manual Sheath Activation by analytical balance
- Simulated Use Study

  This study was performed to confirm that the safety feature of the proposed device can be safely activated by following the Instructions For Use of the device. The study was conducted in a simulated clinical environment and the safety feature activation was performed by healthcare workers with varied amounts of experience. It was concluded that the proposed Terumo SurGuard®3 Safety Hypodermic Needle met its intended use, and the Instructions for Use were adequate for safe and effective activation of the safety feature.

Results of the verification testing performed on both the predicate device and the proposed device met the acceptance criteria of the functional performance tests of both devices.

Shelf Life Testing

Shelf life tests both on the predicate device (K113422) and the proposed Terumo SurGuard®3 Safety Hypodermic Needle and with attached syringe (1cc/ml) were performed using accelerated aged samples to simulate a 5-year (60 months) shelf life for this 510(k) submission. The accelerated aging condition was performed in accordance with ASTM F-1980.

- Sheath Activation
- Sheath Deactivation
- Sheath Removal
- Sheath Radial
- Sheath Retraction
- Protector Fitting
- Collar removal
- Sheath Puncture
- Adhesive Hold
- Needle Penetration
- Manual Sheath Activation
    - Finger Activation
    - Thumb Activation
    - Surface Activation
- Package Seal Strength

Results of verification testing indicated that the functional performance of the proposed Terumo SurGuard®3 Safety Hypodermic Needle and with attached syringe (1cc/ml) is acceptable throughout a 5-year (60months) shelf life. The shelf-life will be confirmed with real time testing.

Biocompatibility Testing

Biocompatibility was established for the Terumo SurGuard®3 Safety Hypodermic Needle manufactured by Terumo (Philippines) Corporation (K113422) which is comprised of blood contacting materials identical to the Terumo SurGuard®3 Safety Hypodermic Needle (26G, 27G and 30G) and with attached syringe (1cc/ml) device. No changes have been made since 510(k) clearance that would require re-testing; therefore, biocompatibility established under K113422 is still applicable.

The Terumo SurGuard®3 Safety Hypodermic Needle is classified as Externally Communicating Device, Circulating Blood, Limited Duration of Contact (≤24hr.). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO – 10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing". Results of the testing demonstrate that the blood contacting materials are biocompatible.

None of the data raises any new issues of safety and effectiveness.

Product Risk Analysis

Additionally a product risk analysis was conducted and there were no new issues of safety and effectiveness.

Conclusion: The performance of the TERUMO SurGuard®3 Safety Needle submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the legally marketed predicate devices. The proposed devices perform as well as the predicate devices.

F. COMPARISON TO STANDARDS

The Terumo SurGuard®3 Safety Hypodermic Needle complies with the requirements specified in the following standards:

- ISO 23908:2011 – Sharps Injury Protection, requirements and test methods – sharps protection features for single hypodermic needles, introducers for catheters, and needles used for blood sampling
- ISO 7886-1:1993 – Sterile Hypodermic Syringes for Single Use
- ISO 594-1:1986 – Conical Fittings with a 6% taper on syringes, needles, and certain other medical equipment
- ISO 6009:1992/Cor:1:2008 – Hypodermic Needles for Single Use – color coding for identification

The Terumo SurGuard®3 Safety Hypodermic Needle also complies with the requirements specified in ISO 7864:1993 – Sterile Hypodermic Needles for Single

Use, with the exception of:

Section 13.2a Patency of Lumen: no specifications are given for 26G, 27G and 30G having an ultra thin wall cannula. As a result, these needles cannot be compared to this requirement.

G. ADDITIONAL SAFETY INFORMATION

Manufacturing controls include visual, functional and sterility tests.

The sterility of the device is assured using a sterilization method validated in accordance with ANSI/AAMI/ISO 11137 – Medical Devices – Validation and Routine Control of Radiation Sterilization. The Terumo SurGuard®3 Safety Hypodermic Needle is sterilized to provide a Sterility Assurance Level (SAL) of 10^{-6}.

A specific sterilization dose to provide Sterility Assurance Level (SAL) of 10^{-6} is set using bioburden information obtained.

H. CONCLUSION

The performance of the TERUMO® SurGuard®3 Safety Needle submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the legally marketed predicate device which is:

1. K113422 TERUMO® SurGuard®3 Safety Hypodermic Needle with or without syringe manufactured by Terumo (Philippines) Corporation.

Differences among the devices do not raise any significant issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Terumo (Philippines) Corporation
C/O Mr. Phillip Michael Lester
Regulatory Affairs Specialist
Terumo Medical Corporation
950 Elkton Boulevard
Elkton, Maryland 21921

AUG 2 8 2012

Re: K122249
Trade/Device Names: TERUMO® SurGuard®3 Safety Needle, 23G, 25G, 26G, 27G and 30G; TERUMO® SurGuard® 3 Hypodermic Syringe with Safety Needle, 1cc/mL
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI, MEG
Dated: July 25, 2012
Received: July 30, 2012

Dear Mr. Lester:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

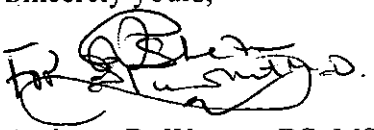
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony B. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122249

Indications for Use

510(k) Number (if known):_____

Device Name: TERUMO® SurGuard®3 Safety Needle, 23G, 25G, 26G, 27G and 30G
TERUMO® SurGuard®3 Hypodermic Syringe with Safety Needle, 1cc/mL

Indications for Use:

The TERUMO® SurGuard®3 Safety Needle device is intended for use in the aspiration and injection of fluids for medical purposes. The TERUMO SurGuard®3 Safety Needle is compatible for use with standard luer slip and luer lock syringes.

Additionally, after withdrawal of the needle from the body, the attached needle safety shield can be manually activated to cover the needle immediately after use to minimize risk of accidental needlestick.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/27/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122249